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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/009,930 | 11/09/2001 | Achim Harder | Mo-6752/LeA 33,583 | 5556 |
| 7590 | 02/08/2005 | | EXAMINER | |
| BAYER PHARMACEUTICALS CORP 400 MORGAN LAND WEST HAVEN, CT 06516-4175 | | | MINNIFIELD, NITA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/009,930 | HARDER ET AL. |
| | Examiner N. M. Minnifield | Art Unit 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 November 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2 and 7-10 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 2 sheets
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 11/4/04 1 sheet

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2004 has been entered.
2. Applicants' amendment filed November 4, 2004 is acknowledged and has been entered. Claim 9 has been amended. Claims 1, 2 and 7-10 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments.
3. Claims 3-6 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed in Paper NO. 7.
4. Receipt is acknowledged of papers (Germany 19921887.0) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (WO 97/09331).

Lee et al discloses compounds (antiparasitic and antimicrobial agents) and compositions useful to inhibit the growth of helminths (abstracts; p. 1; examples). Lee et al discloses a compound with a broad spectrum of activity is particularly advantageous in the treatment of parasitic diseases (p. 3). Lee et al discloses a cyclic depsipeptides (24 ring atoms), which incorporates a piperazine ring (p. 3-4; p. 6; claims). The prior art discloses the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' methods and compositions with the methods and compositions of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and compositions and the methods and compositions of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conder et al 1995 (J. Antibiotics, 1995, 48/8:820-823) taken with Sangster et al 1999 (Parasitology Today, April 1, 1999, 15/4:141-146).

Conder et al teaches the use of cyclodepsipeptide PF1022A as an anthelmintic (abstract). Conder et al teaches that this compound is a potent anthelmintic that can be used in *in vitro* or *in vivo* methods (p. 820; p. 823). Conder et al does not teach the use of the compound piperazine.

However, Sangster et al teaches that piperazine has been used as an anthelmintic in the treatment of horses for example. Sangster et al also discusses

that there is resistance to some anthelmintics and the need to identify other drug compounds to treat parasitic infections and diseases (p. 141). It would have been obvious to a person of ordinary skill in the art the time the invention was made to combine two different anthelmintics in an effort to create compositions that have endoparasiticidal activity, since both of these compounds are known in the art to have this activity. It is well known to prepare combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett* 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in *Crocket* the idea of combining them flows logically from their having been individually taught in prior art. As stated above in the reference Conder et al teach the use of depsipeptide and Sangster et al teaches the use of piperazine, both for the purpose of treating endoparasites. Thus, it would be *prima facie* obvious to one skilled in the art to use separately or in combination the two compounds of the claimed invention, especially since both compounds are known anthelmintics and have endoparasiticidal activity. The claimed invention is *prima facie* obvious in view of the prior art of Conder et al taken with Sangster et al, absent any convincing evidence to the contrary.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
January 31, 2005